IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, *et al.*, **Plaintiffs,** **vs.** **GLAXOSMITHKLINE LLC,** **Defendant.**	**Civil Action No. 2:13-cv-4663-JS**

PLAINTIFFS' OPPOSITION TO GSK'S MOTIONS IN LIMINE REGARDING SB PHARMCO'S GUILTY PLEA AND GSK'S QUI TAM SETTLEMENT (Dkt. Nos. 316 and 317)

GSK has filed two overlapping motions, Dkt. Nos. 316 and 317, regarding SB Pharmco's guilty plea and GSK's qui tam settlement. Both motions should be denied.

We first address Dkt. No. 317 because it is broader than Dkt. No. 316 and effectively subsumes it.

In Dkt. No. 317, GSK moves to exclude (1) all references to SB Pharmco's guilty plea "unless GSK puts the plea at issue by denying" the plea's admissions of guilt; (2) all references to GSK's qui tam settlement; and (3) all references specifically to the $600 million paid by GSK in connection with the qui tam settlement. (Dkt. No. 317 (motion); see also Dkt. No. 317-6 (proposed order).) GSK's motion should be denied because the evidence in question is directly relevant to the nature and extent of GSK's responsibility for what took place at the Cidra plant.

Throughout this litigation, GSK has attempted to distance itself from SB Pharmco and deny responsibility for Cidra's operations. GSK negotiated the admissions made by SB Pharmco in its guilty plea, and GSK expressly agreed to be bound by those admissions under its own "Side Letter Agreement" with the government -- an agreement extracted by the government for

the benefit of insurers such as Plaintiffs and any other private parties that might seek restitution in subsequent litigation against GSK. And yet, in the present case, GSK has repeatedly denied responsibility for SB Pharmco's conduct and denied that GSK is bound by SB Pharmco's admissions. For example, in both its original and amended Answers, GSK has pleaded as a defense: "Defendant is not liable for the liabilities of SB Pharmco nor is Defendant bound by any admissions that may have been made by SB Pharmco." (Dkt. No. 115, at 61; Dkt. No. 211, at 61.) The guilty plea and Side Letter Agreement refute GSK's denials.

Moreover, the guilty plea and qui tam settlement are directly relevant to GSK's statute of limitations defense. The revelation of those settlements in 2010 constituted Plaintiffs' first notice of the fraudulent nature of GSK's conduct at the Cidra plant. Plaintiffs must be allowed to present the plea agreement and qui tam settlement to the jury and contrast what they revealed with what was publicly known before then. The evidence establishes key facts that GSK misrepresented and concealed throughout the relevant period.

In sum, the plea agreement, the plea hearing transcript, the qui tam settlement, and the Side Letter Agreement all are relevant to fundamental issues in this case, and all are essential to any fair assessment of Plaintiffs' claims by the jury.

In GSK's overlapping motion, Dkt. No. 316, GSK moves to exclude SB Pharmco's specific acknowledgment in its plea agreement and during its plea hearing that the government proceedings omitted restitution for private parties. According to GSK, Plaintiffs intend to tell the jury that this acknowledgment "constitutes an admission by GSK that plaintiffs were injured," and that it "adjudicated" GSK's liability to Plaintiffs. (Dkt. No. 316-1, at 3.) That is a fundamental misrepresentation of Plaintiffs' position. Plaintiffs have never asserted that the guilty plea established Plaintiffs' injury or "adjudicated" any liability to Plaintiffs. Instead,

Plaintiffs have properly asserted, and are entitled to inform the jury, that SB Pharmco admitted to specific examples of serious misconduct at Cidra, and GSK is barred from contesting those admitted examples by virtue of its Side Letter Agreement with the government. Whether the admitted examples of misconduct -- along with other proof -- establish Plaintiffs' injury and GSK's liability is a separate question.

As for the plea agreement's specific acknowledgment that the proceedings omitted restitution for private parties, that language obviously has nothing to do with an "adjudication" of liability. The acknowledgment merely established that Plaintiffs and other private parties would not receive a share of GSK's payments to the government. Plaintiffs are entitled to inform the jury of that fact for at least two reasons:

First, GSK has expressly ***invoked*** its payments to the government as proof that GSK has paid its debt to society. For example, GSK recently told the Court in its motion for interlocutory review: "[T]he public interest in this matter has long since been vindicated through a combination of consumer litigation, *qui tam* suits, and a parallel criminal action against SB Pharmco." (Dkt. No. 304-1, at 15.) The jury is entitled to know that private insurers that cover the lion's share of the public's healthcare costs have not yet been "vindicated," and GSK is barred from suggesting otherwise.

Second, GSK has repeatedly characterized any recovery by Plaintiffs in this case as a "multi-billion dollar windfall." (E.g., Dkt. No. 270, at 4 (GSK's Rule 56 brief); Dkt. No. 304-1, at 7 n.1 (GSK's § 1292(b) brief).) Plaintiffs are entitled to inform the jury that private insurers have not yet been compensated for the billions of dollars they paid for GSK's drugs.

I. The Court Should Deny GSK's Motion To Exclude References To SB Pharmco's Guilty Plea And GSK's $600 Million Qui Tam Settlement (Dkt. No. 317)

Both the guilty plea and the qui tam settlement demonstrate GSK's direct responsibility for the misconduct that occurred at Cidra -- something GSK has denied from the start of this litigation. In addition, the guilty plea and qui tam settlement are indispensable evidence of what GSK misrepresented and concealed during the relevant period. GSK will tell the jury that Plaintiffs' claims are barred by the statute of limitations because they had inquiry notice of their claims by July 15, 2007, more than four years before Plaintiffs filed suit. The guilty plea and qui tam settlement rebut GSK's defense. Until the government announced those developments in 2010, Plaintiffs had no reason to suspect the fraudulent nature of GSK's misconduct. GSK cannot be allowed to pursue its defense while Plaintiffs are barred from presenting essential evidence of what remained publicly unknown until 2010.

GSK's arguments for exclusion never address these points. A fair jury trial of Plaintiffs' claims requires denial of GSK's motion.

A. SB Pharmco's guilty plea

GSK argues that SB Pharmco's guilty plea should be excluded entirely "unless GSK puts the plea at issue by denying SB Pharmco's admissions." (Dkt. No. 317-1, at 3, initial capitalization omitted.) GSK asserts that the plea has "minimal probative value" because it "addressed a limited number of lots of only 3 of the 17 At-Issue Drugs" produced "during a brief 19-month period." (*Id*. at 4.) According to GSK, the guilty plea lacks significance regarding anything beyond those isolated batches of three drugs. GSK goes on to declare that connecting the plea to any other aspect of the plant's operations "would necessarily depend on the type of 'if it happened there, it must have happened here' propensity argument that is prohibited under Rule 404(b)." (*Id*.)

That assertion is nonsensical. The guilty plea does not involve "there" vs. "here." It involves only "here." The guilty plea addresses the very same plant, some of the very same drugs, and portions of the very same time period at issue in this case. As GSK knows, Plaintiffs intend to show that the cGMP violations at the plant were systemic, chronic, and pervasive. The guilty plea presents clear and admitted examples of how those violations compromised relevant drugs at relevant times. GSK's reliance on Rule 404(b) exposes the inadequacy of its argument. The Rule provides that "[e]vidence of a crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). But the guilty plea is ***not*** "character" evidence. Plaintiffs have no intention of using it to draw a general inference concerning GSK's "propensity" to engage in misconduct. Instead, the guilty plea is direct and specific evidence of what actually happened within the four walls at Cidra. Rule 404(b) might apply, for example, if Plaintiffs sought to introduce a guilty plea involving one of GSK's other plants. Here, however, Rule 404(b) is irrelevant.

GSK also argues in a footnote that "[a]ny reference to the Paxil CR elements of SB Pharmco's plea should be excluded" because Paxil CR is not one of the At-Issue Drugs. (Dkt. No. 317-1, at 4 n.2.) But again, Plaintiffs intend to show, and they have the undisputed right to show, that the violations at Cidra were systemic and pervasive. Equipment, materials, personnel, and operating procedures involved in producing Paxil CR were also involved in producing At-Issue Drugs. Although Plaintiffs are not seeking damages for Paxil CR, problems relating to that drug demonstrate basic deficiencies in Cidra's plant-wide quality controls that compromised other drugs as well.

Finally, GSK cites Rule 403 and argues that the guilty plea "is likely to confuse and mislead the jury" because it was limited to three At-Issue Drugs and only portions of the relevant period. (Dkt. No. 317-1, at 5.) Here GSK merely repeats its Rule 401 argument, already discussed above. GSK will remain free to point out to the jury the limited scope of the guilty plea. And, contrary to GSK's assertion, it will not take "significant trial time" to do so. (GSK's brief purports to do it in a paragraph.) As for GSK's additional argument that the jury will be confused by the difference in liability elements between the criminal plea and Plaintiffs' civil claims (*id*. at 5-6), the same argument would preclude admission of ***any*** guilty plea in civil litigation. That is plainly not the law. *See, e.g., Westfield Ins. Co. v. Granese*, 2011 WL 346593, at *3-4 (E.D. Pa. Feb. 4, 2011) (guilty plea had collateral estoppel effect in subsequent civil litigation); *Folino v. Young*, 568 A.2d 171, 172 (Pa. 1990) ("This Court has allowed operative facts necessary for non-summary criminal convictions to be admitted as conclusive facts in civil suits arising from the same event."). The jury will be instructed by the Court on the elements of liability in this case. GSK has no basis for suggesting that the jury will fail to understand or misapply the Court's instructions.

B. GSK's qui tam settlement

GSK argues that its qui tam settlement with the government is inadmissible for ***any*** purpose, relying primarily on Rule 408. (Dkt. No. 317-1, at 6-7.) Rule 408, however, contains a general "Exceptions" provision, which states that evidence of a settlement may be admitted for a variety of purposes, "such as proving a witness's bias or prejudice, negating a contention of undue delay, or proving an effort to obstruct a criminal investigation or prosecution." Fed. R. Evid. 408(b). By its terms, the Rule's list of exceptions is illustrative, not exclusive.

GSK itself has already recognized that relevant settlement agreements are admissible in this case. GSK's previous filings have repeatedly cited the FDA's consent decree regarding Cidra -- another settlement agreement that GSK negotiated with the government. GSK's summary judgment motion, for example, cited the consent decree and emphasized its terms: "The FDA did not shutter the Cidra plant or require it to stop production of any At-Issue Drug (except Avandamet temporarily). [Record citation omitted.] Nor did the FDA withdraw its approval for any At-Issue Drug." (Dkt. No. 270, at 10.)

Like the consent decree, GSK's qui tam settlement is relevant and admissible. The agreement establishes a relevant fact that GSK has persistently denied -- its responsibility for SB Pharmco's actions and the misconduct that occurred at Cidra. GSK negotiated and entered into the agreement and paid the $600 million settlement amount. Plaintiffs intend to offer the agreement not as an admission of liability, but rather as evidence of GSK's connection to the events in question. Whether those events establish liability is a separate question, to be proven with other evidence. GSK will have ample opportunity to contest Plaintiffs' evidence of liability. What it cannot do, however, is deny its relationship with Cidra while preventing Plaintiffs from referring to GSK's role in negotiating and paying for the settlement of claims relating to Cidra.

This also disposes of GSK's argument that the settlement agreement is irrelevant under Rules 401 and 402. Once again, GSK misstates Plaintiffs' intentions. As already discussed, the agreement will not be offered as "an admission of liability or wrongdoing." (Dkt. No. 317-1, at 7.) Similarly, GSK misstates the risk that the agreement will cause unfair prejudice and jury confusion. (*Id*. at 7-8.) GSK lacks any basis for suggesting that the jury will conclude that the

agreement constitutes an admission of liability, particularly when GSK can show the jury the provision in the agreement that ***expressly disclaims*** any admission of liability.

Finally, GSK argues that even if the Court allows the jury to see and hear evidence relating to the settlement agreement, it should withhold from the jury the $600 million settlement amount. (*Id*. at 8-9.) Here GSK repeats its invocation of Rule 408 and its arguments regarding relevance, unfair prejudice, and jury confusion under Rules 401 and 403. The amount of the qui tam settlement will demonstrate to the jury that the settlement did not involve an administrative slap on the wrist. GSK repeatedly argues in this case -- and indeed, in this very motion -- that the conduct at issue in the criminal proceedings was limited and insignificant. Likewise, GSK has consistently minimized the violations found by the FDA during its inspections, and even the far broader range of violations that were found by Quantic, a third-party auditor, towards the end of the relevant period. GSK can continue to minimize its misconduct before the jury, but at the same time it should not be allowed to conceal from the jury how much it paid for those supposedly limited and insignificant events when it settled the qui tam case. Furthermore, the jury can be instructed that the settlement amount has no bearing on how much Plaintiffs are entitled to recover -- an amount Plaintiffs will establish by other evidence.

II. The Court Should Deny GSK's Motion To Exclude References To The Acknowledgment In SB Pharmco's Plea Agreement That The Government's Proceedings Did Not Provide Restitution For Private Parties (Dkt. No. 316)

SB Pharmco's plea agreement contained the following provision:

> [T]he parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to any non-federal victims in this case ***given that numerous unknown individuals and insurance companies purchased or reimbursed for the drug products in question, and that tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible***. *See* 18 U.S.C. §

> 3663(a)(1)(B)(ii). Accordingly, the United States agrees that it will not seek a separate restitution order as to SB Pharmco as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

(Dkt. No. 316-1, Ex. 1, at 3, ¶ 4.d, emphasis added.) As GSK notes, this acknowledgment was confirmed at SB Pharmco's plea hearing. (Dkt. No. 316-1, at 2.)

In connection with SB Pharmco's guilty plea, GSK entered into a "Side Letter Agreement" with the government in which (a) GSK acknowledged that SB Pharmco was admitting to the crime charged in the Information, and (b) GSK agreed not to make any "statements inconsistent with this explicit admission of guilt by SB Pharmco to the crime charged in the Information." (Dkt. No. 316-1, Ex. 3.) The latter provision had an obvious and important purpose: to prevent GSK from denying SB Pharmco's admissions of guilt in any subsequent litigation against GSK in which healthcare insurers or other private parties might seek the restitution explicitly omitted in the government's proceedings.

GSK's motion fundamentally misrepresents what Plaintiffs have said -- and intend to say at trial -- about the plea agreement in general, about its acknowledgment regarding restitution for private parties, and about GSK's Side Letter Agreement. According to GSK, Plaintiffs have asserted that the guilty plea "adjudicated" GSK's liability ***to Plaintiffs***, and this supposed adjudication is "premised *solely* on the restitution-related language" in the plea agreement. (Dkt. No. 316-1, at 3, emphasis in original.) GSK's assertions are doubly false:

First, Plaintiffs have never taken the position that the guilty plea "adjudicated" any liability to Plaintiffs; if that were the case, Plaintiffs would have moved for summary judgment accordingly. Instead, Plaintiffs have taken the entirely legitimate position -- and are entitled to inform the jury -- that SB Pharmco admitted to specific examples of serious misconduct at Cidra, and GSK is barred from contesting those admitted examples by virtue of the Side Letter

Agreement. Whether the admitted examples establish GSK's liability to Plaintiffs is a different issue. Simply put, the asserted "adjudication" of liability is a figment of GSK's imagination.

Second, GSK's statement that Plaintiffs have "premised" this imaginary adjudication on the plea agreement's specific language regarding the absence of restitution for private parties is equally baseless. GSK's liability depends on the evidence of events at Cidra. ***Some*** of those events were admitted by SB Pharmco's guilty plea and cannot be disputed now by GSK; ***other*** events (and the rest of Plaintiffs' prima facie case) will be presented through other evidence; but ***none*** of those events will be proven by the absence-of-restitution language in the plea agreement, which says nothing about what happened at Cidra.

Nevertheless, the restitution-related language remains relevant for other purposes. GSK paid $150 million to settle the criminal case and another $600 million to settle the qui tam litigation. In the present case, GSK has expressly ***invoked*** those payments as proof that GSK has paid its debt to society. Less than a month ago, GSK told this Court: "[T]he public interest in this matter has long since been vindicated through a combination of consumer litigation, *qui tam* suits, and a parallel criminal action against SB Pharmco." (Dkt. No. 304-1, at 15 (GSK's § 1292(b) brief).) The jury is entitled to know that the government proceedings against SB Pharmco and GSK did ***not*** result in any remedy for private plaintiffs, and GSK admitted as much in an agreement it negotiated with the government.

Furthermore, GSK has repeatedly attacked any recovery by Plaintiffs in this case as a "multi-billion dollar windfall." (E.g., Dkt. No. 270, at 4 (GSK's Rule 56 brief); Dkt. No. 304-1, at 7 n.1 (GSK's § 1292(b) brief).) The same attack will undoubtedly become a recurring theme at trial. For that reason as well, Plaintiffs are entitled to inform the jury that private insurers have not yet received a dollar in compensation from GSK.

Conclusion

The Court should deny GSK's two motions in limine regarding SB Pharmco's guilty plea and GSK's qui tam settlement, Dkt. Nos. 316 and 317.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on November 1, 2019 I served the foregoing Plaintiffs' Opposition to GSK's Motions in Limine Regarding SB Pharmco's Guilty Plea and GSK's Qui Tam Settlement (Dkt. Nos. 316 and 317) by email on the following counsel:

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